DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 1, 2014

Medtronic Sofamor Danek USA, Incorporated
Ms. Shweta Sharma
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K142450
Trade/Device Name: DIVERGENCE™ Anterior Cervical Fusion System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ, ODP
Dated: August 29, 2014
Received: September 2, 2014

Dear Ms. Sharma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142450

Device Name
DIVERGENCE™ Anterior Cervical Fusion System

Indications for Use *(Describe)*
The DIVERGENCE™ anterior cervical plate and bone screw components are intended for anterior interbody screw fixation from C2-T1. The plate and bone screw components are indicated for use in the temporary stabilization of the anterior spine during the development of spinal fusions in patients with: 1) degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), 2) trauma (including fractures), 3) tumors, 4) deformity (defined as kyphosis, lordosis, or scoliosis), 5) pseudoarthrosis, and/or 6) failed previous fusions.

The DIVERGENCE™ anterior cervical cage component is intended to be used for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. This cage is to be used in patients who have had six weeks of non-operative treatment. The DIVERGENCE™ cage must be used with supplemental fixation. The DIVERGENCE™ cage is also required to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and is to be implanted via an open, anterior approach.

When used together, the DIVERGENCE™ components can be used only to treat cervical disc disease.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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DIVERGENCE™ Anterior Cervical Fusion System
510(k) Summary

September 29, 2014

I.	**Company:**	Medtronic Sofamor Danek USA, Inc. 1800 Pyramid Place Memphis, TN 38132 Phone: (901) 396-3133 Fax: (901) 346-9738
	Contact Person:	Shweta Sharma Senior Regulatory Affairs Specialist
II.	**Proprietary Trade Name:**	DIVERGENCE™ Anterior Cervical Fusion System
	Common Name:	Cervical Intervertebral Fusion Device with Bone Graft
	Classification Name:	21 CFR 888.3060 – Spinal Intervertebral Body Fixation Orthosis 21 CFR 888.3080 - Intervertebral Body Fusion Device
	Regulatory Class:	Class II
	Product Codes:	KWQ, ODP
III.	**Predicate Device:**	DIVERGENCE™ Anterior Cervical Fusion System (K140417, SE 07/09/2014) This predicate has not been subject to a design-related recall. This predicate is the primary predicate for this submission. No reference devices are provided in this submission.

IV. Device Description:

The DIVERGENCE™ Anterior Cervical Fusion System consists of temporary implants (plates and bone screws) intended for anterior screw fixation, and fusion devices (interbody cages) intended to stabilize and promote bone fusion during the normal healing process following surgical correction of disorders of the spine.

The DIVERGENCE™ anterior cervical plates and bone screws are available in broad range of size offerings that are intended for anterior screw fixation intended for stabilization use during the normal healing process following surgical correction of disorders of the spine. Fixation is provided by bone screws inserted into the vertebral body of the cervical spine using an anterior approach. The DIVERGENCE™ anterior cervical plate and bone screws are made from titanium alloy and are provided sterile.

The DIVERGENCE™ anterior cervical cages available in various widths and heights can be inserted between two cervical vertebral bodies to give support and correction during cervical interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. These implants must be used with supplemental fixation. The device is made from medical grade polyetheretherketone (PEEK OPTIMA™ LT1), contains titanium alloy wire markers and is provided sterile.

The associated accessories include:

- Guides
- Inserters
- Trials

The purpose of this submission is to introduce new implant trials into the DIVERGENCE™ Anterior Cervical Fusion System.

V. Indications for Use:

The DIVERGENCE™ anterior cervical plate and bone screw components are intended for anterior interbody screw fixation from C2-T1. The plate and bone screw components are indicated for use in the temporary stabilization of the anterior spine during the development of spinal fusions in patients with: 1) degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), 2) trauma (including fractures), 3) tumors, 4) deformity (defined as kyphosis, lordosis, or scoliosis), 5) pseudoarthrosis, and/or 6) failed previous fusions.

The DIVERGENCE™ anterior cervical cage component is intended to be used for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. This cage is to be used in patients who have had six weeks of non-operative treatment. The DIVERGENCE™ cage must be used with supplemental fixation. The DIVERGENCE™ cage is also required to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and is to be implanted via an open, anterior approach.

When used together, the DIVERGENCE™ components can be used only to treat cervical disc disease.

VI. Comparison of Technology Characteristics with the Predicate Device

The subject interbody trials are substantially equivalent to the predicate DIVERGENCE™ Anterior Cervical Fusion System (K140417, SE 07/09/2014) The subject DIVERGENCE™ Anterior Cervical Fusion System devices have the same dimensions, indications, intended use, fundamental scientific technology, surgical technique, labeling, method of use, sterilization, packaging and material as the

predicate DIVERGENCE™ Anterior Cervical Fusion System (K140417, SE 07/09/2014). Like the predicate DIVERGENCE® Anterior Cervical Fusion System trials, the subject trials will be provided non-sterile and will be manufactured from medical grade stainless steel with silicone handles. Also like the predicate device, the subject devices are also used to identify the best fit implant for the fusion procedure.

The difference between the predicate and subject device is that the predicate trials are modular, single-ended in design as compared to the one-piece, dual-ended design of the subject trials.

VII. Performance Data

A risk analysis and validation labs of the design modifications were completed in accordance with Medtronic design control procedures. The risk analysis, which included an engineering rationale, demonstrated that the subject DIVERGENCE™ Anterior Cervical Fusion System does not introduce new issues of safety or effectiveness.

VIII. Conclusion

A risk analysis and an engineering rationale were completed for the subject devices. Based on the verification/validation results and additional supporting documentation provided in this submission, the subject devices demonstrated substantial equivalence to the previously listed predicate device.